510(k) Summary of Safety and Effectiveness

JUN 26 2006

Applicant Name and Address: Collagen Matrix, Inc.
509 Commerce Street
Franklin Lakes, New Jersey 07417

Contact Person: Peggy Hansen, RAC
Director, Clinical, Regulatory, and Quality Assurance
Tel: (201) 405-1477
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Date of Summary: May 30, 2006

Device Common Name: Collagen Dura Substitute Membranes

Device Trade Name: DuraMatrix™ Collagen Dura Substitute Membranes

Device Classification Name: Dura substitute
Class II
882.5910
GXQ

Predicate Device(s): DuraMatrix™ Collagen Dura Substitute Membrane, K040888

Description of the Device

The Collagen Dura Substitute Membrane are white, nonfriable, conformable, resorbable, membrane matrices engineered from highly purified type I collagen derived from bovine Achilles tendon. The devices have thicknesses similar to that of native dura. They are flexible and conform to the contours of the defect site. The Collagen Dura Substitute Membranes are supplied sterile, non-pyrogenic, in various sizes, and for single use only.

Intended Use

The Collagen Dura Substitute Membranes are indicated for use as a dural substitute for the repair of dura mater.

Summary/Comparison of Technical Characteristics

Collagen Dura Substitute Membranes and their predicate have similar technological characteristics. In particular, the Collagen Dura Substitute Membrane and its predicates are similar with respect to intended use, material, form, sizes, thickness, physical integrity, pore structure and conformability.

Safety

Collagen Dura Substitute Membrane equivalent has been evaluated by a number of tests to assess its safety/biocompatibility. The device passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

Effectiveness

The results of a large-scale animal study and clinical study of the equivalent product support the effectiveness of using a membrane material as a dura substitute in the repair of dura mater. The characteristics of the modified Collagen Dura Substitute Membranes meet the design requirements for an effective dura substitute.

Conclusion

The results of the *in vitro* product characterization studies show that the device modifications of the Collagen Dura Substitute Membrane are safe and substantially equivalent to the original device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2006

Collagen Matrix, Inc.
c/o Peggy Hansen, RAC
Director, Clinical, Regulatory, and Quality Assurance
509 Commerce Street
Franklin Lakes, New Jersey 07417

Re: K061487
Trade/Device Name: DuraMatrix™ Collagen Dura substitute Membranes
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: June 7, 2006
Received: June 8, 2006

Dear Ms. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Brennan
for

Mark Melkerson
Director
Division of General, Restorative
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061487

Device Name: DuraMatrix™ Collagen Dura Substitute Membranes

Indications for Use:

DuraMatrix™ Collagen Dura Substitute Membranes are indicated as dural substitutes for the repair of dura mater.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061487